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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,206	12/16/2004	Pingyun Y. Chen	P51364	3204
20462	7590	07/13/2006	EXAMINER	
SMITHKLINE BEECHAM CORPORATION				AULAKH, CHARANJIT
CORPORATE INTELLECTUAL PROPERTY-US, UW2220				ART UNIT
P. O. BOX 1539				PAPER NUMBER
KING OF PRUSSIA, PA 19406-0939				1625

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/518,206	CHEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 07 April 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-40 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-40 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/7/06 and 1/30/06.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

### **DETAILED ACTION**

1. According to paper filed on April 7, 2006, the applicants have amended claim 1.
2. Claims 1-40 are pending in the application.

#### ***Response to Arguments***

3. Applicant's arguments filed on April 7, 2006 have been fully considered but they are not persuasive regarding prior art rejections as well as regarding obviousness rejections. In regard to prior art rejection, the examiner does not agree with the applicants arguments that the examiner did not set forth a *prima facie* basis for the statement that instant hydrate and anhydrous forms will not be maintained in pharmaceutical composition as well as following *in vivo* administration. The utility of treating hypertension and angina pectoris using instant hydrate and anhydrous forms of carvedilol is identical to the utility of free base form of carvedilol disclosed by Wiedemann. The utility of carvedilol is due to the compound itself and not due to hydrate or anhydrous form. The applicants did not provide any evidence that hydrate form and anhydrous form of carvedilol will be maintained in pharmaceutical composition or following *in vivo* administration.

In regard to obviousness rejection, the examiner does not agree with the applicants arguments that Hildesheim does not provide any motivation to one skilled in the art to prepare the instant carvedilol hydrobromide hydrate, salt, solvate or anhydrate. The applicants admit that Hildesheim teaches preparing carvedilol hydrochloride hydrate form ( see page 9, last three lines ). The only difference between the instant compounds and the compounds of Hildesheim is the salt. As stated clearly in the last

office action, Hildesheim teaches the advantages of polymorphs, hydrates and solvates such as solubility in aqueous solution, the ease of processing the form into pharmaceutical dosages etc. and therefore, provides the motivation to prepare different crystalline hydrate and solvate forms of carvedilol.

***Conclusion***

4. Rejection of claims 35-40 under 35 U.S.C. 102(b) is maintained for the reasons of record.
5. Rejection of claims 1-40 under 35 U.S.C. 103(a) is maintained for the reasons of record.
6. The provisional ODP rejection of claims 1-40 is maintained for the reasons of record.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

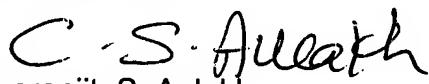
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625